IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Ann-Kristin Karlsson et al. Art Unit : Unknown
Serial No. : Not yet assigned Examiner : Unknown
Filed : November 27, 2001
Title : NEW COMPOSITION OF MATTER

Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Prior to examination, please amend the application as follows:

In the specification:

Page 1, line 1, above "Field of the Invention" insert the following:

-- CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation (and claims the benefit of priority under 35 USC §120) of U.S. application 09/230,781, filed January 29, 1999. --

In the claims:

Cancel claims 1, 2, 5, 7, 13, and 15-29.

Amend claims 3, 4, 6, 8-12, 14, 30, and 31 as follows:

3. (Amended) A pharmaceutically acceptable powder in the form of dry finely divided particles having a mass median diameter (MMD) of less than 10 μm, said powder being sterilized and comprising a glucocorticosteroid or ester, acetal, or salt thereof, wherein the glucocorticosteroid or ester, acetal, or salt thereof comprises an asymmetric acetal structure.

4. (Amended) The powder according to claim 3, said dry powder containing greater than 98.5% by weight of the glucocorticosteroid or ester, acetal, or salt thereof.

6. (Amended) The powder according to claim 3, wherein the glucocorticosteroid or ester, acetal, or salt thereof is selected from the group consisting of budesonide, rofleponide and rofleponide palmitate.

8. (Amended) A sterile pharmaceutical formulation comprising a pharmaceutically acceptable powder in the form of dry finely divided particles, said powder being sterilized and comprising a glucocorticosteroid or ester, acetal, or salt thereof, wherein the glucocorticosteroid or ester, acetal, or salt thereof comprises an asymmetric acetal structure, and wherein at least 80% of the particles have a mass median diameter (MMD) of less than 10 μm.

9. (Amended) The sterile pharmaceutical formulation according to claim 8, further comprising one or more pharmaceutically acceptable additives, diluents or carriers.

10. (Amended) The sterile pharmaceutical formulation according to claim 8, comprising at least one additive selected from the group consisting of surfactants, pH regulating agents, chelating agents, agents rendering the suspension isotonic and thickening agents.

11. (Amended) The sterile pharmaceutical formulation according to claim 8, wherein the concentration of the glucocorticosteroid or ester, acetal, or salt thereof ranges from about 0.05 to about 20 mg/ml.

12. (Amended) The sterile pharmaceutical formulation according to claim 8, wherein the glucocorticosteroid is an anti-inflammatory glucocorticosteroid.

14. (Amended) The sterile pharmaceutical formulation according to claim 8, wherein the glucocorticosteroid or ester, acetal, or salt thereof is selected from the group consisting of budesonide, rofleponide and rofleponide palmitate.

30. (Amended) A method for treatment of an allergic and/or inflammatory condition of the nose or lungs comprising administering to a mammal suffering from such a condition a therapeutically effective amount of a powder according to claim 3.

31. (Amended) A method for treatment of chronic obstructive pulmonary disease (COPD), rhinitis or asthma comprising administering to a mammal suffering from such a condition a therapeutically effective amount of a powder according to claim 3.

Add claims 32-48 as follows:

--32. The powder according to claim 3, wherein the particles have a mass median diameter (MMD) of less than 5 μm.--

--33. The powder according to claim 3, wherein the particles have a mass median diameter (MMD) of less than 1 μm.--

--34. The powder according to claim 3, said powder comprising greater than 99.2% of the glucocorticosteroid or ester, acetal, or salt thereof.--

--35. The powder according to claim 3, wherein the glucocorticosteroid is budesonide or ester, acetal, or salt thereof.--

--36. The powder according to claim 3, wherein the powder is suitable for administration in nasal or oral inhalation.--

--37. The sterile pharmaceutical formulation according to claim 11, wherein at least 60% of the particles have a mass median diameter (MMD) of less than 4 μm.--

--38. The sterile pharmaceutical formulation according to claim 8, wherein the concentration of the glucocorticosteroid or ester, acetal, or salt thereof ranges from about 0.1 to about 5 mg/ml.--

--39. A pharmaceutically acceptable powder in the form of dry finely divided particles having a mass median diameter (MMD) of less than 10 μm, said powder being sterilized by heat treatment at a temperature of from 100°C to 130°C and comprising a glucocorticosteroid or ester,

acetal, or salt thereof, wherein the glucocorticosteroid or ester, acetal, or salt thereof comprises an asymmetric acetal structure.--

--40. The powder according to claim 39, wherein the particles have a mass median diameter (MMD) of less than 5 μm.--

--41. The powder according to claim 39, wherein the powder is sterilized by heat treatment for no more than 4 hours.--

--42. The powder according to claim 39, wherein the powder is sterilized by heat treatment at a temperature of about 120°C for no more than 2 hours.--

--43. A method for treatment of an allergic and/or inflammatory condition of the nose or lungs comprising administering to a mammal suffering from such a condition a therapeutically effective amount of a formulation according to claim 8.--

--44. A method for treatment of chronic obstructive pulmonary disease (COPD), rhinitis or asthma comprising administering to a mammal suffering from such a condition a therapeutically effective amount of a formulation according to claim 8.--

--45. The powder according to claim 39, wherein the glucocorticosteroid or ester, acetal, or salt thereof is selected from the group consisting of budesonide, rofleponide and rofleponide palmitate.--

--46. The powder according to claim 39, wherein the glucocorticosteroid or ester, acetal, or salt thereof contains less than about 0.5% (w/w) of water before the heat treatment.--

-- 47. The powder according to claim 3, wherein the asymmetric acetal structure comprises 16α,17α-butylidenedioxy.--

-- 48. The powder according to claim 8, wherein the asymmetric acetal structure comprises 16α,17α-butylidenedioxy.--

In the abstract:

Replace the abstract with the following version.

-- The invention provides sterile glucocorticosteroids and sterile formulations containing glucocorticosteroid and use thereof in the treatment of an allergic and/or inflammatory condition of the nose or the lungs. --

REMARKS

Applicants have filed herewith a continuation application, claiming priority from the parent application (USSN 09/230,781). Claims 1, 2, 5, 7, 13, and 15-29 have been cancelled without prejudice. Applicants have amended claims 3, 4, 6, 8-12, 14, 30 and 31 and added claims 32-48. Support for amended claims 3 and 8 and new claim 39 appears at page 3, line 29 to page 4, line 3; page 4, line 30 to page 5, line 3; and page 5, lines 6-9 of the specification. Claims 4, 6, 9-12, 14, 30, and 31 have been amended to eliminate multiple claim dependency and to more particularly point out and more distinctly claim the subject matter of the invention. As to new claims 32-48, support comes from original claims 3, 4, 5, 8, 11, 13, 18, 21-24, 26, 27, 30 and 31 as well as page 5, lines 3-9 and lines17-25, page 6, lines 23-26 and page 7, lines 21-23 of the specification. No new matter has been added.

Attached is a marked-up version of the changes being made by the current amendment.

Claims 3, 4, 6, 8-12, 14, and 30-48 are now pending. Prompt examination of the claims, as amended, is respectfully requested. Please apply any other charges or credits to Deposit Account No. 06-1050, referencing Attorney's Docket No. 06275-160002.

Respectfully submitted,

Date: Nov 27, 2001

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Version with markings to show changes made

In Insert the following paragraph above "Field of the Invention" at page 1, line 1.

-- CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation (and claims the benefit of priority under 35 USC §120) of U.S. application 09/230,781, filed January 29, 1999. --

In the claims:

Claims 1, 2, 5, 7, 13, and 15-29 have been cancelled without prejudice.

Claims 3, 4, 6, 8-12, 14, 30, and 31 have been amended as follows:

3. (Amended) [The glucocorticosteroid according to claim 1 or 2] A pharmaceutically acceptable powder in the form of dry finely divided particles having a mass median diameter (MMD) of less than 10 μm[, preferably less than 5 μm], said powder being sterilized and comprising a glucocorticosteroid or ester, acetal, or salt thereof, wherein the glucocorticosteroid or ester, acetal, or salt thereof comprises an asymmetric acetal structure.

4. (Amended) The [glucocorticosteroid] powder according to [any previous claim having a purity greater than 98.5%] claim 3, said dry powder containing greater than 98.5% by weight of the glucocorticosteroid or ester, acetal, or salt thereof [preferably greater than 99.2% by weight].

6. (Amended) The [glucocorticosteroid] powder according to claim [5] 3, wherein the glucocorticosteroid [with] or ester, acetal, or salt thereof [contains an asymmetric acetal structure] is selected from the group consisting of budesonide, rofleponide and rofleponide palmitate.

8. (Amended) [The] A sterile pharmaceutical formulation [according to claim 7] comprising a pharmaceutically acceptable powder in the form of dry finely divided particles, said powder being sterilized and comprising a glucocorticosteroid or ester, acetal, or salt thereof,

wherein the glucocorticosteroid or ester, acetal, or salt thereof comprises an asymmetric acetal structure, and wherein at least 80% of the [glucocorticosteroid] particles have a mass median diameter (MMD) of less than 10 μm[, preferably at least 60% less than 4 μm].

9. (Amended) The sterile pharmaceutical formulation according to claim [7 or] 8, further comprising one or more pharmaceutically acceptable additives, diluents or carriers.

10. (Amended) The sterile pharmaceutical formulation according to [any of claims 7 to 9] claim 8, comprising at least one additive selected from the group consisting of surfactants, pH regulating agents, chelating agents, agents rendering the suspension isotonic and thickening agents.

11. (Amended) The sterile pharmaceutical formulation according to [any one of claims 7 to 10] claim 8, [comprising] wherein the concentration of the glucocorticosteroid or ester, acetal, or salt thereof ranges from about 0.05 to about 20 mg/ml [of the glucocorticosteroid, preferably from 0.1 to 5 mg/ml of the glucocorticosteroid].

12. (Amended) The sterile pharmaceutical formulation according to [any one of claims 7 to 10] claim 8, wherein the glucocorticosteroid is an anti-inflammatory glucocorticosteroid.

14. (Amended) The sterile pharmaceutical formulation according to claim [13] 8, wherein the glucocorticosteroid [with an asymmetric acetal structure] or ester, acetal, or salt thereof is selected from the group consisting of budesonide, rofleponide and rofleponide palmitate.

30. (Amended) A [Method] method for treatment of an allergic and/or inflammatory condition of the nose or lungs comprising administering to a mammal suffering from such a condition a therapeutically effective amount of a [glucocorticosteroid] powder according to [any one of claims 1 to 6] claim 3 [or a formulation according to any one of claims 7 to 14].

31. (Amended) A [Method] method for treatment of chronic obstructive pulmonary disease (COPD), rhinitis or asthma comprising administering to a mammal suffering from such a condition a therapeutically effective amount of a [glucocorticosteroid] powder according to claim 3 [or a formulation according to claim 30].

In the abstract:

The invention provides [a process for the sterilization of a powdered form of a glucocorticosteroid,] sterile glucocorticosteroids[,] and sterile formulations containing glucocorticosteroid and use thereof in the treatment of an allergic and/or inflammatory condition of the nose or the lungs.